DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
D12 51 B

San Francisco District
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Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-50181

March 11, 1997

Thomas C. DeJong
Chris DeJong Dairy
14763 Road 168
Porterville, CA 93257

WARNING LETTER

Dear Mr. DeJong:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 30, 1996, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On November 11, 1996, you consigned a dairy cow (identified by USDA laboratory report number 385933) for sale for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed sulfadimethoxine in the muscle at 0.79 parts per million (ppm) and in the liver at 0.67 parts per million (ppm). The tolerance level for sulfadimethoxine in the edible tissues of cattle is 0.1 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are

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Porterville, California

ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in their species or class.

The Albon brand sulfadimethoxine boluses that you use to treat your dairy cows, are adulterated under Section 501(a)(5) of the Act in that they are new animal drugs within the meaning of Section 201(w) and are unsafe within the meaning of Section 512(a)(1)(B) of the Act since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses on the first day followed by one bolus per day for three to four days. The labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to an adequate withdrawal time is likely the cause of the presence of the violative levels of sulfadimethoxine in the tissues of the animal you sold for food use.

You are using the drug Dur-Vet brand of penicillin G procaine in a manner not in conformance with approved labeling. Penicillin G Procaine labeling prescribes a dosage of 1 ml. per 100 pounds of body weight and warns against using more than 10 ml. per injection site. Your practice of administering two 40 to 50 ml injections per day in one site in an animal results in a dosage in excess of that allowed by the labeling. This overdosing presents a possibility that illegal residues will occur.

You are using the drug Tetra-Bac 324 brand of tetracycline hydrochloride powder in a manner not in conformance with approved labeling. Tetra-Bac 324 is not approved for use in lactating dairy cows. Your practice of mixing this product with water to prepare a interuterine infusion for use in your cattle is an unapproved use for which safety and efficacy

have not been established. Creating the infusion constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to adhere to the instructions for use is likely the cause of the illegal residues found in the animals you sold for slaughter. Failure to comply with the label instructions on the drugs you use to treat your animals makes the drugs unsafe.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrections now may result in enforcement action without further notice, including seizure and/or injunction.

Your firm has a history of offering calves and cull cows for sale for human use which have been found to be adulterated with antibiotic drug residues. According to USDA reports, during the period of October 1, 1993, through December 1, 1995, you're firm delivered three cows for food use which were found to contain illegal drug residues. During this same period, you also sold a calf which was found to be CAST positive An inspection was conducted of you're dairy on February 12, 1991. During the inspection you were warned that it is illegal to market animals with harmful levels of drugs. A Notice of Adverse Findings Letter, dated, April 12, 1991, was sent to you as a result of the violations found during that inspection. Also, the U.S. Department of Agriculture sent you a letter for each instance in which their analysis found violative levels drugs. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Robert J. Anderson, Investigator.

Sincerely yours,

for Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]